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Siggaard, Lene Dahl; Barrett, Thomas Qvist; Luscher, Michael; Tingsgaard, Peter Koefoed; Homoe, Preben

Published in:
Danish Medical Journal

Publication date:
2019

Document Version
Publisher's PDF, also known as Version of record

[Link to publication from Aalborg University](#)

Citation for published version (APA):

Siggaard, L. D., Barrett, T. Q., Luscher, M., Tingsgaard, P. K., & Homoe, P. (2019). Specialists' adherence to guidelines on tympanostomy tube insertion. *Danish Medical Journal*, 66(9), [A5552].
<http://ugeskriftet.dk/dmj/specialists-adherence-guidelines-tympanostomy-tube-insertion>

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Specialists' adherence to guidelines on tympanostomy tube insertion

Lene Dahl Siggaard¹, Thomas Qvist Barrett², Michael Lüscher³, Peter Koefoed Tingsgaard⁴ & Preben Homøe⁵

ABSTRACT

INTRODUCTION: Tympanostomy tube insertion is very frequent in Denmark. Using electronic patient-reported outcome (ePRO) data, we investigated Danish ear, nose & throat (ENT) specialists' adherence to the 2015 national clinical guideline (NCG) on first-time tympanostomy tube (TT) insertion in children aged 0-5 years with otitis media (OM).

METHODS: Data on children aged 0-5 years with OM undergoing first-time TT insertion were extracted from the Danish ENT Specialists Organisation (DØNHØ) database. Pre-operative questionnaires were used to obtain information on symptom duration, and the number of acute OM (AOM) episodes was analysed. The following criteria were established to define NCG adherence: 1) A symptom duration of three months or longer, 2) three or more AOM episodes within six months and 3) four or more AOM episodes within 12 months. These criteria are in accordance with the NCG definition of chronic OM with effusion (COME) and recurrent AOM (RAOM).

RESULTS: A total of 1,495 children were included in the study. In total, 91.0% of the parents reported a symptom duration of three months or more and/or RAOM within 6-12 months prior to TT insertion in accordance with the adherence criteria; 4.6% reported a symptom duration of less than three months with few or no episodes of AOM and did not meet the recommended TT insertion criteria. Finally, 4.4% of the parents were undecided with respect to symptom duration, number of AOM episodes or both at 6-12 months prior to TT insertion.

CONCLUSIONS: Using solely ePRO data, we found that Danish practicing ENT specialists adhere to the 2015 NCG in regard to OM symptom duration and RAOM.

FUNDING: none.

TRIAL REGISTRATION: not relevant.

Tympanostomy tube (TT) insertion is a well-established and frequent treatment option for children suffering from otitis media (OM). OM comprises acute OM (AOM), OM with effusion (OME) and chronic OME with effusion (COME) and is estimated to affect at least 60% of Danish pre-school aged children [1]. A recent Danish study found an average annual number of 36,196 TT insertions in approximately 19,000 children aged 0-15 years between 1997 and 2011 [2]. The same

study predicted that at least 24% of Danish children would undergo TT insertion before the age of three years. Private practicing ear, nose & throat (ENT) specialists perform the vast majority of these TT insertions, whereas a minor part is performed at hospitals.

According to another Danish study, socio-economic factors such as reduced smoking, prolonged maternity leave, higher welfare and introduction of childhood vaccines have improved in the past 30 years [1]. As these factors are risk factors for OM, a reduction in OM incidence would be expected. Contrarily, more children spend more time in day-care centres today than 30 years ago, which may balance-out the influence of the decrease in OM risk factors. The extent to which these factors affect the incidence of OM and consequently the TT insertion frequency in Danish children remains unclear [1]. Even so, the total number of TT insertions performed nationally has declined slightly and gradually since 2010 according to data from Danish Regions. This may, in part, be explained by the introduction of the pneumococcal conjugate 13-valent vaccine (PCV13) in 2010 [3]. Despite considerable regional differences in the number of procedures performed, Denmark still has the highest registered rate of TT insertion per habitant in the world [2, 4].

Owing to a Danish Consensus Conference in 1987, the first national approach to a standardised treatment strategy for children with OME was prepared. However, this guideline did not include children with RAOM, and general uncertainty remained regarding correct identification of patients best suited for surgical candidacy [5]. In 2015, the Danish Health Authority published a new national clinical guideline (NCG) on TT insertion in children aged 0-5 years with COME and/or RAOM [6]. The recommendations for TT insertion are listed in **Table 1**.

The present study aimed to explore if electronic parent-reported outcome (ePRO) data may be used to evaluate private Danish ENT specialists' adherence to the 2015 NCG on children with OM based on symptom duration and number of AOM episodes prior to TT insertion.

METHODS

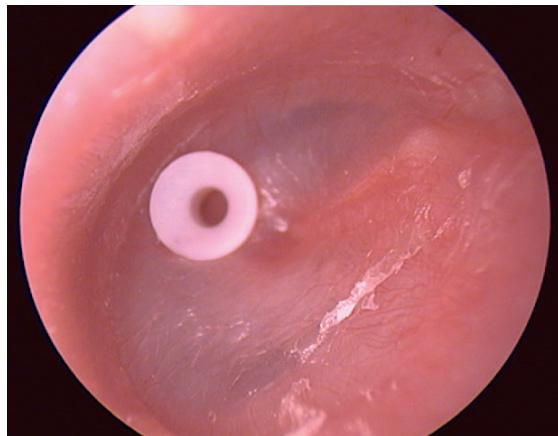
Data were extracted from the Danish ENT Specialists

ORIGINAL ARTICLE

- 1) Department of Otorhinolaryngology, Aalborg University Hospital
- 2) ENT Private Clinic, Randers
- 3) ENT Private Clinic, Aarhus
- 4) ENT Private Clinic, Slagelse
- 5) Department of Otorhinolaryngology and Maxillofacial Surgery, Zealand University Hospital, Køge, Denmark

Dan Med J
2019;66(9):A5552

Tympanostomy tube inserted in eardrum.



Organisation (DØNHØ) database, which was established as a pilot project in 2017 by a group of 26 Danish private ENT specialists. Data were collected using the Danish National Tympanostomy Tube Insertion Questionnaires (DANTIQ). The database currently contains the first pre- and post-operative ePRO data on more than 3,500 children below 12 years of age in whom TT insertion was performed under general anaesthesia in private ENT practice settings between March 2017 and August 2018. The database is currently growing since patient registration and data collection are on-going. If needed, the database can be expanded prospectively to include all 160 Danish private ENT specialists.

The parent or caregiver of every child gave consent to participate at the pre-operative consultation with the

ENT specialist. The clinic staff registered patients in the database. In- and exclusion criteria are shown in **Table 2**. Data were encrypted and stored anonymously in the database. A link to the pre-operative questionnaire was emailed to the parents two days prior to surgery enquiring about the number of AOM episodes within the year preceding surgery; parents were also asked to tick off a list of ear-related symptoms and state the duration of these symptoms. Post-operative follow-up questionnaires were sent one month after TT insertion and thereafter planned at three-month intervals for a total of two years of follow up [7].

To match the patient population described in the NCG and thus evaluate guideline adherence, we analysed the pre-operative ePRO data of children aged 0-5 years offered first-time TT insertion and whose parents had completed the pre-operative questionnaire. We established three criteria according to the definitions of COME and RAOM in the NCG to define NCG adherence: 1) Symptom duration of three months or longer, 2) three or more episodes of AOM within six months or 3) four or more episodes of AOM within 12 months.

The DANTIQ were developed by a group of Danish ENT specialists and have subsequently been validated in a separate study [8].

The Bio-statistical Advisory Service at the University Hospital in Aarhus, Denmark, performed all statistical analyses. Confidence intervals were calculated for all proportions.

The study and the registration database were approved by the Danish Data Protection Agency (no. 2016-42-3152). Ethical approval was not required under Danish Law.

Trial registration: not relevant.

RESULTS

A total of 3,553 children < 12 years were registered during the observation period. In compliance with the study's inclusion criteria, 1,495 children aged 0-5 years were included. Their median age was 16 months (range: 4-71 months), 56.7% (n = 848) were boys and 43.3% (n = 647) were girls. An exact pre-operative response rate could not be calculated as information regarding prior TT insertion had not been obtained at the time of registration. However, based on analysis on treatment effects in the same 3,553 children < 12 years presented elsewhere, a response rate of 75.3% regarding pre-operative questionnaires was found [6].

Results regarding symptom duration and number of AOM episodes up to one year prior to TT insertion are presented in **Table 3**. The group of children not meeting the NCG recommendation criteria on TT insertion was considered too small to be included in a comparative sub-group analysis.

TABLE 1

Summary of the Danish 2015 national clinical guideline recommendation on tympanostomy tube insertion in children aged 0-5 years with otitis media.

| Recommendation | Strength | Overall evidence quality |
|---|----------|--------------------------|
| <i>Surgical management of COME</i> | | |
| Consider offering TT to children with bilateral COME and hearing problems with or without concurrent speech problems | ↑ | + |
| Pending careful consideration, TT insertion should be offered only to children with COME and behavioural problems, vestibular problems or lowered quality of life if the child has normal hearing, as the effect is uncertain | ↓ | + |
| Pending careful consideration, TT insertion should be offered only to children with COME and no other symptoms since there is no evidence of a beneficial effect | ↓ | + |
| <i>Surgical management of RAOM</i> | | |
| Consider TT insertion in children with RAOM with or without middle ear effusion between AOM episodes | ↑ | ++ |

AOM = acute otitis media; COME = chronic otitis media with effusion; RAOM = recurrent acute otitis media; TT = tympanostomy tube.

↑: weak recommendation for treatment.

↓: weak recommendation against treatment.

+: low-quality level of evidence.

++: very low-quality level of evidence [5].

TABLE 2

| | DØNHO database | Study population | Criteria for inclusion and exclusion of children in the DØNHO database and the present study on ear, nose & throat specialists' adherence to the Danish 2015 national clinical guideline on tympanostomy tube insertion. |
|----------------------------------|---|---|--|
| <i>Criteria of participation</i> | | | |
| Inclusion | Children aged 0-11 yrs undergoing TT insertion in GA | Children aged 0-5 yrs undergoing first-time TT insertion in GA | |
| Exclusion | Children aged ≥ 12 yrs Parents without an e-mail address Parent with insufficient language capabilities Parents who did not wish to participate Parents with insufficient cognitive capabilities Parents with illiteracy | Children aged ≥ 6 yrs Parents without an e-mail address Parents with insufficient language capabilities Parents who did not wish to participate Parents with insufficient cognitive capabilities Parents with illiteracy | |
| <i>Questionnaires</i> | | | |
| Preoperative | 2 days before surgery | 2 days before surgery | |
| Post-operative | After 1 mo. After 3, 6, 9, 12, 15, 18, 21, 24 mo.s | - | |

DØNHO = Danish ear, nose & throat specialist organisation; GA = general anaesthesia; TT = tympanostomy tube.

DISCUSSION

Our main result shows good ENT specialist adherence to NCG recommendations with respect to symptom duration and number of AOM episodes up to one year prior to TT insertion based on ePRO data.

The literature does not report agreement on a minimally acceptable response rate [9]. However, a pre-operative response rate of 75.3% introduces a risk of non-response bias. Even so, we believe that our relatively large study sample is sufficiently representative, why the negative effects of non-response bias are diminished.

ePRO data have been acknowledged as a potential tool for inclusion of the patient's experience into the clinical decision-making process in the treatment of cancer patients [10]. ePRO data have also been used as a tool for evaluating short-term treatment effect following TT insertion in children below 12 years of age [7]. In the present study, ePRO data provided real-time and un-biased answers by caregivers to children 0-5 years of age who were offered TT insertion. In this group of children who themselves cannot provide information, caregiver response is particularly useful. In addition, ePRO data collection is fast, easily executed, cost-effective and time-efficient for all participating parties [7]. Although patient inclusion was preceded by an ENT specialist's assessment and thus conditional to having TT insertion performed, clinical observations and examinations such as hearing-threshold measurements and mobility assessments of the tympanic membrane were not registered in the database. This is important when interpreting the results.

The Danish NCG recommends the use of TT insertion in children with OME when effusion persists for three months or longer (COME) and when a concurrent hearing loss is documented [6]. We found that 91.0% of the parents reported a symptom duration of three

TABLE 3

Private ear, nose & throat specialists' adherence to the Danish 2015 national clinical guideline on tympanostomy tube insertion in children aged 0-5 years with otitis media assessed by electronic patient-reported outcome data on symptom duration and number of acute otitis media episodes prior to surgery (N = 1,495).

| | n | % (95% CI) |
|--|-------|------------------|
| <i>Adherence to NCG recommendations</i> | | |
| Symptom duration ≥ 3 mo.s and/or concurrent RAOM | 1,318 | 88.2 (86.4-89.8) |
| Symptom duration ≥ 3 mo.s and unknown number of AOM episodes | 27 | 1.8 (1.2-2.6) |
| RAOM and symptom duration < 3 mo.s | 12 | 0.8 (0.4-1.4) |
| RAOM and unknown symptom duration | 3 | 0.2 (0.04-0.6) |
| <i>Deviation from NCG recommendations</i> | | |
| Symptom duration < 3 mo.s and no concurrent RAOM | 69 | 4.6 (3.6-4.8) |
| Symptom duration < 3 mo.s and unknown number of AOM episodes | 4 | 0.3 (0.07-0.7) |
| Unknown symptom duration and no concurrent RAOM | 57 | 3.8 (2.9-4.9) |
| Unknown symptom duration and number of AOM episodes | 5 | 0.3 (0.1-0.8) |

AOM = acute otitis media; CI = confidence interval; NCG = national clinical guideline; RAOM = recurrent AOM.

months or longer prior to TT insertion, which is in accordance with the NCG definition of COME. As parental observation has been found to correlate well with Danish private ENT specialists' estimation of symptom duration [11], it seems reasonable to conclude from our findings that physicians adhere well to the NCG recommendation in regard to symptom duration.

Data on physician-tested hearing loss were not registered in the present study, and data on hearing loss rely solely on the parents' reports on pre-operative "sense of hearing loss" as is the nature of ePRO data. Parents' reports on hearing loss have been shown to be of debatable value [12, 13]. In Denmark, it is the intention that hearing-threshold measurements form an integrated part of ENT specialists' assessment programme in children with OM prior to medical or surgical treatment. In the present study, knowledge of

potential hearing loss prior to TT insertion would therefore have been beneficial. However, other ear-related problems aside from hearing loss seem important as shown in a study on the short-term effect of TT insertion in children with OM, where significant relief in symptoms such as interrupted sleep and earache was found [7]. This implies that TT insertion has an effect on other symptoms associated with COME and RAOM than hearing loss. Based on this, we disregarded data on parent-reported hearing loss in the present study.

The Danish NCG is almost identical to international clinical practice guidelines in regard to recommendations for TT insertion in children with COME [6, 14, 15]. The clinical practice guideline of the American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF) and the guideline on surgical management of children with OME of the UK National Institute of Clinical Excellence (NICE) both recommend TT insertion in children with bilateral COME and concurrent, documented hearing loss, and/or other symptoms likely caused by or attributable to COME; e.g. physical, cognitive or behavioural issues leading to speech, language or learning difficulties [14, 15]. Direct evidence on TT insertion in children with RAOM is limited, and international guideline recommendations vary slightly. However, Danish and American guidelines both favour TT insertion in children with middle-ear effusion between AOM episodes [6, 14].

In 2010, Johansen et al [11] investigated private ENT specialists' adherence to the Danish guideline recommendation on TT insertion from 1987. A group of 426 children aged 0-6 years who underwent first-time TT insertion were included. Of these, 80% were observed by a general practitioner or an ENT specialist for three months or longer before surgery, which was in agreement with the current guideline recommendation.

In 2017, Hughes et al [16] evaluated the appropriateness of TT insertion and American ENT specialists' guideline adherence to the AAO-HNSF clinical practice guideline on TT insertion in a group of 120 children aged less than nine years who underwent TT insertion. The study reported 75% adherence to the AAO-HNSF guideline, but in 5% TT insertion substantially deviated from the guideline.

In 2015, Daniel et al [17] examined British ENT specialists' adherence to the NICE guidelines on surgical management of COME by retrospectively studying the records of 319 children aged less than 12 years with TT insertion. The study reported only 32% complete adherence to the NICE guideline's so-called "core criteria" regarding COME-attributed hearing loss (two audiograms obtained at a three-month interval with a hearing level in the better ear at 25-30 dB normal hearing level or poorer). However, accordance with NICE

guidelines rose to 87% if exceptional cases were included, e.g. cases with developmental, social or educational status issues caused by the presence of COME. The high number of children having TTs due to exceptional circumstances led to the conclusion that clinicians were adapting the treatment to the individual child's needs. It also implied that these cases were more the norm than the exception.

There seems to be a well-established international consensus that COME-attributed hearing loss is the main reason for TT insertion in children [6, 14, 15, 18]. However, in everyday clinical practice, ENT specialists and parents may base their treatment decision on the children's general well-being as well as on symptoms such as interrupted sleep and earache when offering TT insertion in children with OM [19, 20].

Our study is based on ePRO data and is susceptible to selection bias on the part of the parents, who may prefer TT insertion. The study design did not include a control group, and the absence of data on potential hearing loss is a limitation. To strengthen the validity of the study, hearing-threshold measurements and mobility assessment of the tympanic membrane are needed. However, we believe that our data show a surgical treatment trend among Danish private ENT specialists that seems to adhere extensively to the Danish 2015 NCG on TT insertion in children aged 0-5 years with OM.

Unfortunately, recommendations on TT insertion are based on studies that are neither controlled nor randomised [6]. Available evidence is sparse, and guideline adherence alone cannot guarantee correct use of TT insertion. Until more substantial evidence is presented, guideline interpretation must be done carefully and additional criteria may evolve. TT insertion should be preceded by a thorough parent-reported symptom history as well as a standardised ENT specialist assessment. Monitoring of this by, e.g., use of ePRO data, is important.

CONCLUSIONS

With respect to parent-reported symptom duration and/or RAOM alone without reference to hearing threshold measurements pre-operatively, private ENT specialists seem to adhere well to the 2015 NCG on TT insertion in children aged 0-5 years with OM.

Optimal evaluation of guideline adherence would require a pre-operative hearing test; however, as this report relied solely on ePRO data, analysis of such data was beyond the scope of the study.

Finally, ePRO data are a promising tool for monitoring adherence to guidelines among private ENT specialists in Denmark.

CORRESPONDENCE: Lene Dahl Siggaard.
E-mail: lenedahlsiggaard@gmail.com

ACCEPTED: 16 May 2019

CONFLICTS OF INTEREST: none. Disclosure forms provided by the authors are available with the full text of this article at Ugeskriftet.dk/dmj

ACKNOWLEDGEMENTS: We express our gratitude towards the private practicing ENT specialists in the pilot clinics* for their implementation of patient registration in the database. We also greatly appreciate our valuable collaboration with the Danish ENT Specialists Organisation (DØNHØ), the Unit of Quality in Specialist Practice, eKVIS, and the Fund for Professional Development in Specialist Practice who have been of great support in setting up and implementing the DØNHØ database.

*) *Pascal Bonvin*, Aalborg, *Mikkel Bruun*, Aalborg, *Janus Jespersen*, Aalborg, *Peder Frandsen*, Aalborg, *Christian Bak*, Viborg, *Jakob Korsholm Nielsen*, Randers, *Jonas Peter Holm*, Randers, *Thomas Qvist Barrett*, Randers, *Malene Sine Rokkjær*, Aarhus, *Michael Lüscher*, Aarhus, *Jette Berg*, Aarhus, *Bo Karlsmose*, Aarhus, *Andreas Agger*, Horsens, *Torben Lilholt/Rikke Haahr* (shared practice), Horsens, *Berit Svenstrup*, Svendborg, *Pia Juul*, Odense, *Lotte Jung*, Odense, *Peter Koefoed Tingsgaard*, Slagelse, *Liviu Guldred*, Faxe, *Kim Werther*, Roskilde, *Tomaas Ravn*, Copenhagen, *Ann-Louise Reventlow-Mourier*, Copenhagen, *Anders Schermacher*, Gentofte, *Christian Prætorius*, Hørsholm, *Roland Welinder*, Hørsholm & *Mikkel Holmelund*, Elsinore.

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